House of Representatives

General Assembly

File No. 161

January Session, 2013

House Bill No. 5347

House of Representatives, March 26, 2013

The Committee on General Law reported through REP. BARAM of the 15th Dist., Chairperson of the Committee on the part of the House, that the bill ought to pass.

AN ACT CONCERNING PRESCRIPTION DRUG LABELS.

Be it enacted by the Senate and House of Representatives in General Assembly convened:

Section 1. Section 20-617 of the general statutes is repealed and the following is substituted in lieu thereof (*Effective January 1, 2014*):

(a) Each pharmacist shall include on the label of each prescription container: (1) The quantity of prescribed drug placed in such container, in addition to any other information required by law; and (2) a prominently printed expiration date based on the manufacturer's recommended conditions of use and storage that can be read and understood by the ordinary individual. The expiration date required pursuant to subdivision (2) of this section shall be no later than the expiration date determined by the manufacturer.

(b) If a nonbrand name drug is dispensed, each pharmacist shall include the name of the brand name and name of the generic drug on the label of the prescription container. The information required pursuant to this subsection shall be in the following form, with the

generic name and brand name inserted as appropriate: "_____ Generic for _____."

This act shall take effect as follows and shall amend the following sections:		
Section 1	*January 1, 2014*	20-617

GL *Joint Favorable*

OFA Fiscal Note

State Impact: None

Municipal Impact: None

Explanation

There is no fiscal impact to the Department of Consumer Protection (DCP) in requiring pharmacists to label generic prescription drugs with both the generic name of the drug and the brand name as the DCP already acts upon related consumer complaints and few additional complaints are anticipated.

The Out Years

State Impact: None

Municipal Impact: None

OLR Bill Analysis

HB 5347

AN ACT CONCERNING PRESCRIPTION DRUG LABELS.

SUMMARY:

This bill requires pharmacists to label generic prescription drugs with both the generic name of the drug and the brand name, in the form: "_____ Generic for _____." Currently, the brand name is not required on generic drug labels.

EFFECTIVE DATE: January 1, 2014

BACKGROUND

Related Law - FDA Regulation of Prescription Drug Labeling

The U.S. Food and Drug Administration (FDA) regulates prescription drug labeling and preempts state regulation in some areas. The U.S. Supreme Court ruled that the FDA did not have exclusive jurisdiction over prescription drug labeling in a case that allowed a lawsuit for damages to proceed against a brand name drug manufacturer based on a state law claim of inadequate warning labels (*Wyeth v. Levine*, 129 S.Ct. 1187 (2009)). But, the Court found that a similar state law claim against a generic manufacturer conflicted with and was preempted by federal regulations that required generic drug labels to be identical to FDA-approved labels (*Pliva, Inc. v. Mensing*, 131 S.Ct. 2567 (2011)). The preempted suit could have resulted in requiring a generic drug manufacturer to update labeling to reflect newly discovered side effects, something the manufacturer could not legally do alone, without the FDA acting.

COMMITTEE ACTION

General Law Committee

Joint Favorable

Yea 15 Nay 3 (03/12/2013)